DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District d2015b
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2937518

September 3, 1998

Russell Morgan, President
RC Mor / All Med
3878 Stanley Blvd.
Pleasanton, CA 94566

WARNING LETTER

Dear Mr. Morgan:

During an August 20 and 28, 1998 inspection of your firm, All Med, located at 3878 Stanley Blvd., Pleasanton, CA 94566, Food and Drug Administration Investigator Carl A. Anderson documented deviations from the Good Manufacturing Practice Regulations as outlined in Title 21 Code of Federal Regulations, Part 211 in conjunction with your firm's repacking of Oxygen, USP. These deviations cause the drug to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. You have failed to establish a Quality Control Unit [21 CFR 211.22(a)-(d)]. No employee of your firm has been trained to perform quality control. As such, the written procedures you have established for your facility have not been reviewed and signed by a Quality Control Unit. The section of your written procedures addressing Quality Assessment and Improvement have not adequately assigned duties and responsibilities and do not describe the duties and procedures of the Quality Control Unit.

2. You have failed to follow written procedures [21 CFR 211.100(a)(b)]. Although you are currently transporting and refilling Oxygen, USP, on August 20, 1998 you could not locate written procedures for your firm's operations. The written procedures you provided on August 28, 1998 had not been reviewed or updated since October 27, 1994. The written procedures and there is no documentation of deviations. For

example: you have not established a Quality Assessment and Improvement Committee; you have not determined monitoring methods; you have not documented prefill inspections on cryogenic home vessels; and you have not maintained adequate distribution records.

3. There is only one employee at the firm performing work with medical gas. There is no second person to review or supervise work. You have failed to establish a training program or adequate personnel qualifications. There is no documentation of any training activities by the firm [21 CFR 211.25(a)(c)].

4. You have failed to assay incoming liquid oxygen for identity and strength prior to filling home units [21 CFR 210.165(a)]. Your firm relied on the supplier for the complete testing of the Oxygen, USP and you have failed to conduct audits of the supplier's test method and you have not received training in the supplier's test method.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure adherence with all requirements of the Act and that regulations are being met.

Enclosed are a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Outline and 21 CFR Part 211. You were provided with a copy of "Fresh Air '98" by Mr. Duane Sylvia of FDA's Office of Compliance, Division of Manufacturing and Product Quality, Center for Drug Evaluation and Research at the conclusion of your inspection by Investigator Anderson. Mr. Sylvia's speech and Compressed Medical Gases Outline contain useful information on how to comply with the requirements of 21 CFR Part 211.

Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products (Section 304) and for Injunction (Section 302) of the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time needed to complete the corrections.

Please submit your response to the Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070, attention: Steven R. Gillenwater, Medical Gas Monitor.

Sincerely,

Patricia C. Ziobro
District Director

Enclosures:

21 CFR Part 211
Compressed Medical Gases Guideline